



AMENDMENT UNDER 37 C.F.R. §1.111  
U.S. Appln. No. 10/627,757

Q76319

**REMARKS**

Claims 1-8, 10 and 12-13 are all the claims pending in the application; each of the claims has been rejected.

Support for the amendment of claim 1 to recite detection of a mutation at either position 619 or 898 of SEQ ID NO:1 can be found through the specification, such as at page 8, last paragraph. Support for the amendment of claim 1 to recite detection of “open angle” glaucoma can be found at page 4, paragraph “7”, of the specification.

Support for the amendment of claim 2 to recite a specific mutation at position 619 may be found at page 4, paragraph “3”, of the specification.

Support for the amendment of claim 4 to recite the use of the primers set forth in SEQ ID NOS:21 and 22 to detect the mutation at position 619 may be found in Table 1, where it is disclosed that the mutation at position 619 is found in exon 7, and at page 16, lines 7-10, where it is indicated that the primers of SEQ ID NOS:21 and 22 amplify exon 7.

Support for the amendment of claim 5 to recite the use of the primers set forth in SEQ ID NOS:27 and 28 to detect the mutation at position 898 may be found in Table 1, where it is disclosed that the mutation at position 898 is found in exon 10, and at page 16, lines 19-22, where it is indicated that the primers of SEQ ID NOS:27 and 28 amplify exon 10.

No new matter has been added. Entry of the amendment is respectfully requested.

**I. Claim Rejections Under 35 U.S.C. § 112, First Paragraph - Written Description**

At paragraph 2 of the Office Action, claims 1-8, 10, 12, and 13 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The Examiner states that the claims are drawn to a method for predicting an increased risk for onset of any type of glaucoma based on the detection of any mutation in the coding region of any OPTN gene of any subject using a variety of primers.

Included herewith is an amendment to the claims such that the subject matter of the claims is a method for predicting an increased risk for onset of open angle glaucoma in a human subject by detecting a mutation at position 619 or 898 of SEQ ID NO:1. The amended claims thus recite a method of predicting the onset of a specific disease, in a specific patient population

by screening for at least one of two specific mutations in one specific gene. The amended claims thus recite a well-defined method that is limited in scope to one disease, one patient population, one gene and at least one of two mutations.

In view of the amendment to the claims, and the points discussed above, it is clear that the claims have adequate written description support in the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

## **II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph - Enablement**

At paragraph 3 of the Office Action, claims 1-8, 10, 12, and 13 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner again states that the claims are drawn to a method for predicting an increased risk for onset of any type of glaucoma based on the detection of any mutation in the coding region of any OPTN gene of any subject using a variety of primers.

As indicated above, included herewith is an amendment to the claims such that the subject matter of the claims is a method for predicting an increased risk for onset of open angle glaucoma in a human subject by detecting a mutation at position 619 or 898 of SEQ ID NO:1. The amended claims thus recite a method of predicting the onset of a specific disease, in a specific patient population by screening for at least one of two specific mutations in one specific gene. The amended claims thus recite a well-defined method that is limited in scope to one disease, one patient population, one gene and two mutations.

The skilled artisan would be readily enabled to practice the full-scope of the invention as it is now being claimed.

In a discussion at page 8, last paragraph, of the Office Action, the Examiner suggested that the data provided in Example 2 of the specification (pages 18-19) was lacking in details regarding the patient population. Applicants include herewith a Declaration Under 37 C.F.R. §1.132 by one of the inventors, Yasuhiro Kouchi. The numbers of patients in the different patient populations discussed in Example 2 of the specification (pages 18-19) are provided in the Declaration.

In view of the amendment to the claims, and the additional evidence provided in the Declaration, it is clear that the skilled artisan would have been enabled to practice the full scope

of the invention as recited in the claims at the time the application was filed. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**III. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph - Indefiniteness**

At paragraph 5 of the Office Action, claims 10, 12, and 13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Included herewith is an amendment to the claims canceling claims 10, 12 and 13, thus making this rejection moot.

In view of the cancellation of claims 10, 12 and 13, Applicants respectfully request reconsideration and withdrawal of this rejection.

**IV. Claim Rejections Under 35 U.S.C. § 102 - Anticipation**

**A.** At paragraph 7 of the Office Action, claims 1, 2 and 4-8 are rejected under 35 U.S.C. § 102(e) as being anticipated by Sarfarazi et al. (U.S. Patent Application Publication No. 2004/0191798).

The Examiner states that Sarfarazi teaches a method for predicting an increased risk for onset of glaucoma by assaying for the presence of a mutation in at least one nucleotide of an OPTN gene.

Applicants note that Sarfarazi discloses that the risk for onset of glaucoma can be predicted by detecting particular mutations (a change from GAG to AAG at codon 50, insertion of AG after codon 127, a change from CGG to CAG at codon 545, etc.) of the optineurin sequence.

Sarfarazi does not, however, disclose a means for predicting an increased risk for the onset of open angle glaucoma, much less by assaying for the presence of a mutation at either position 619 or 898 of the OPTN gene, as recited in claim 1. Nor does Sarfarazi disclose the specific mutations at these positions as recited in claims 2 and 3, or the primers recited in claims 4 and 5 for use in the method recited in claim 1.

Because Sarfarazi does not teach each and every limitation of the claims, as amended, Sarfarazi does not anticipate the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**B.** At paragraph 8 of the Office Action, claims 1, 2, 5, 7 and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rezaie et al. (Science, 2002).

The Examiner states that Rezaie teaches a method of assaying for mutations in the coding region of the OPTN gene of a subject. The Examiner further states that Rezaie teaches that three OPTN mutations were found to be disease-causing mutations for adult onset POAG, and that a fourth mutation was associated with the risk of developing glaucoma.

Applicants note that Rezaie discloses that particular mutations in the OPTN gene (G458A, insertion of AG at 691-692, G1994A) are disease-causing alternations for POAG. Rezaie also describes that T603A is a risk-associated alteration for POAG.

Rezaie does not, however, describe a method for predicting an increased risk for onset of open angle glaucoma, much less by assaying for the present of a mutation at either position 619 or 898 of the OPTN gene, as recited in claim 1. Nor does Rezaie disclose the specific mutations at these positions as recited in claims 2 and 3, or the primers recited in claims 4 and 5 for use in the method recited in claim 1.

Because Rezaie does not teach each and every limitation of the claims, as amended, Rezaie does not anticipate the claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **V. Claim Rejections Under 35 U.S.C. § 103**

At paragraph 11 of the Office Action, claims 10 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sarfarazi in view of Genbank Accession No. NT 031849 (February 2002).

Included herewith is an amendment to the claims canceling claims 10 and 12, thus making this rejection moot.

In view of the cancellation of claims 10 and 12, Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **VI. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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